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K011192

ALLIANCE
MEDICAL CORPORATION

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Phoenix, Arizona 85044

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510(k) Summary of Safety and Effectiveness

Submitter: Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact: Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation: 28 August 2001

Name of device: Reprocessed Compression Sleeves

Common Name: Compression Sleeve

Classification Name: Compressible Limb Sleeve

Reprocessed Device(s):

Manufacturer	Model
Healthcare Service and Supply	ALP-1
	ALP-2
	ALP-3
	ALP-4
Huntleigh Healthcare	Flowtron DVT10
	Flowtron DVT20
	Flowtron DVT30
	Flowtron DVT40
Kendall	Impad 5046
	Impad 5048
	Impad 5057
	Impad 5059
	SCD 5329
	SCD 5330
	SCD 5345
	SCD 5480
	SCD 6329
	SCD 6330
	SCD 6345
	SCD 6480

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Reprocessed Devices, (continued)	Venodyne	V2012 V2014 V2022 V2026 V3012 V3014 V3022 V3026

Predicate device(s):	**K932835**	Kendall T.E.D./SCD
	K974318	ALP Alternating Leg Pressure Pump and Garments for the Limb
	K000303	Healthcare Service and Supply ALP® Garments for the Limb
	K925717	Huntleigh Healthcare, Inc., Calf Garment DVT 10 Compressible Limb Sleeve
	K890938	Kendall SCD Therapeutic System
	K953648	Kendall Healthcare Products A-V Impulse System®, with Impad® Rigid Sole Foot Cover
	K942664	Kendall SCD Sequel Compression System
	K992079	Kendall SCD Response™ Compression System
	K881632	Huntleigh Technology DVT System AC500
	K970014	Trinity Huntleigh Pump Compatible Sleeves
	K930526	Microtek Medical, Inc., Venodyne Model 510

Device description: Compression sleeves are part of an external compression system, in which intermittent or sequential compression is provided using a pump/controller and limb garment. The system consists of the following three main components: a control unit, inflatable limb sleeves and conduit tubing with detachable connections.

Intended use: The Reprocessed Compression Sleeve is intended to help prevent deep vein thrombosis and pulmonary embolism by supplying a measured, intermittent pressure into the compression sleeve worn on the lower extremities of a recumbent patient, resulting in a repetitive squeezing and relaxing action, simulating normal muscle contraction.

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Indications statement:

Reprocessed Compression Sleeves are indicated for use in providing external compression therapy to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism in patients at risk for thrombosis formation.

Technological characteristics:

The design, materials, and intended use of the Reprocessed Compression Sleeve are identical to the predicate devices. The mechanism of action of the Reprocessed Compression Sleeve is identical to the predicate devices in that the same standard mechanical design, materials and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Alliance Medical Corporation's reprocessing of Compression Sleeves includes removal of adherent visible soil and decontamination. Each individual compression sleeve is tested for appropriate function of its components prior to packaging, labeling, and sterilization operations.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Compression Sleeve.

- Biocompatibility
- Validation of reprocessing
- Leak Decay Testing

Performance testing demonstrates that Reprocessed Compression Sleeves perform as originally intended.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed Compression Sleeve) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Don Selvey
Vice President
Regulatory Affairs and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, AZ 85044

Re: K011192
Trade Name: Reprocessed Compression Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: August 28, 2001
Received: August 31, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

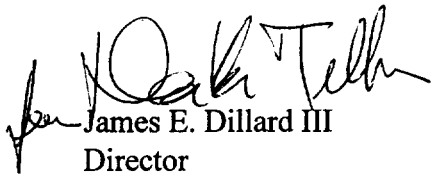
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K011192

Device Name: Alliance Medical Corporation Reprocessed Compression Sleeve

Indications for Use: Reprocessed Compression Sleeves are indicated for use in providing external compression therapy to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism in patients at risk for thrombosis formation.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011192

Prescription Use ✓ or Over-the-Counter Use ____
(per 21 CFR 801.109)